

FRAUD & ABUSE

Medicare Fraud Strike Force: Past, Present, and Future

Peter Katz, Esquire
Berkeley Research Group
New York, NY

In March 2007, the Medicare Fraud Strike Force (Strike Force) originated in South Florida as a ground-breaking joint effort between the U.S. Department of Justice's (DOJ's) Criminal Division Fraud Section, the U.S. Attorney's Office for the Southern District of Florida, U.S. Department of Health and Human Services, Office of Inspector General, as well as state and local law enforcement agencies to prosecute individuals and businesses that did not provide legitimate healthcare services, but existed and operated for the sole purpose of stealing money from the Medicare coffers.

Over the last four years, this first-of-its-kind strike force in the healthcare arena has become a model of innovation in terms of strategy, methodology, and practice. By virtually any measure, the Strike Force has been a success. According to DOJ, as of September 2011, the Strike Force, now in nine cities, has charged more than 1140 defendants who have collectively billed the Medicare program for more than \$2.9 billion and stolen approximately half that amount. In addition, hundreds of millions of dollars have been returned to the Medicare Trust Fund through restitution and forfeiture. Such accomplishments are that much more impressive when one considers that the Strike Force has fewer than two dozen prosecutors conducting these investigations nationwide.

The Medicare System

On July 30, 1965, Medicare and its companion program Medicaid were signed into law by President Lyndon Johnson as part of his "Great Society." Former President Harry Truman was the first to enroll in Medicare. His Medicare Part B premium was \$3 per month.¹

Medicare was formed as an optional insurance plan administered by the federal government designed to provide coverage for medically necessary services such as physician services, hospital inpatient care, outpatient care, physical therapy, durable medical equipment (DME), as well as preventative services such as exams, lab tests, and vaccines to help prevent, find, or manage a medical problem.

Recent statistics indicate that more than forty-seven million Americans are Medicare beneficiaries.² Approximately 590,000 healthcare providers billed Medicare Part B (outpatient services).³ Payment to those providers just from Medicare Part B amounted to approximately \$66 billion.⁴ By many accounts, as much as 10% of all expenditures, or more than \$6 billion per year, is due to fraudulent billings.⁵

Table of Contents

Medicare Fraud Strike Force: Past, Present, and Future <i>Peter Katz, Esq.</i>	1
Darned If You Do and Darned If You Don't: Perspectives on the Benefits and Dangers of the CMS Self-Referral Disclosure Protocol <i>Rebecca Matthews, Esq.</i> <i>Jody Erdfarb, Esq.</i>	5
Turning a Blind Eye to Overpayments: Not Worth the Gamble <i>Barbara J. Zabawa,</i> <i>JD, MPH, FACHE</i>	8
Dr. Scott Harkonen, Former CEO of InterMune, Appeals His Criminal Conviction and Exclusion by OIG <i>Laurence Freedman, Esq.</i> <i>Cordell Hull, Esq.</i>	11
Chair's Two Cents <i>Mark Bonanno, Esq.</i>	12
Fraud and Abuse Practice Group Goes Live on Twitter! <i>Anthony Choe, Esq., MPH</i> <i>Matthew Fisher, Esq.</i> <i>Gary Herschman, Esq.</i>	13



Fraud & Abuse © 2012 is published by the American Health Lawyers Association. All rights reserved. No part of this publication may be reproduced in any form except by prior written permission from the publisher. Printed in the United States of America. "This publication is designed to provide accurate and authoritative information in regard to the subject matter covered. It is provided with the understanding that the publisher is not engaged in rendering legal or other professional services. If legal advice or other expert assistance is required, the services of a competent professional person should be sought."
—from a declaration of the American Bar Association

Strategy

For the first thirty years after Medicare was enacted, federal prosecutors went about healthcare prosecution the same way that they did with most insider trading, bank robberies, illegal immigration, and gun and drug trafficking investigations—each U.S. Attorney's Office dealt with each case on an ad hoc basis, conducting a thorough and complete investigation of their targets, case by case. There was no coordination of effort and no unified theory of prosecution. Cases were made the old-fashioned way, often beginning with cooperating witnesses and co-conspirators, investigating the crime after it had been completed. While the Anti-Kickback Statute was enacted in the 1970s, it was sparingly used. In addition, no federal statute more generally criminalized healthcare fraud during this period. From a prosecutorial standpoint, there was good reason not to focus on healthcare fraud—during this period healthcare costs, and concomitantly, healthcare fraud, were relatively low. In other words, there was no pressing need.

In the early 1990s, that all changed. From 1991 through 1993, healthcare costs increased approximately twice as fast as the gross domestic product (GDP).⁶ Healthcare fraud, therefore, increased at approximately the same rate. With those increased costs came increased attention to healthcare-related expenditures, including attacking healthcare fraud. So, in 1996, the federal government broadened the Health Insurance Portability and Accountability Act of 1996 to extend criminal penalties to inducements to refer to any federal healthcare insurance program, including insurers and providers. Congress enacted Title 18, United States Code, Section 1347, which, for the first time, specifically criminalized any scheme to defraud a healthcare benefit program. By 1998, DOJ began to establish both criminal and civil healthcare fraud coordinators in all ninety-four U.S. Attorneys' offices, beginning the trend to unify and standardize national healthcare investigations and prosecutions.

After a modest increase in healthcare costs in the mid-1990s, from 1999 through the first ten years of the twenty-first century, healthcare costs doubled in addition to growing again at twice the GDP.⁷ Again, much attention was focused on eliminating fraud from the national healthcare system. This time, with the underlying legal fabric in place, federal law enforcement established a unified, focused team of investigators and prosecutors to combat the problem. This tactic was new to healthcare prosecution, but had been effective in many other areas.

The notion of focusing law enforcement manpower and dollars to combat a focused, specific problem is centuries old. One lasting example stems from 1865, when the U.S. Secret Service was created to suppress the counterfeiting of U.S. currency. It was estimated that after the Civil War, up to one third of all currency certificates (bills) in circulation were counterfeit.⁸ While its mandate has expanded over time, for almost 150 years the Secret Service has all but eradicated counterfeit currency through traditional investigative techniques, new criminal sanctions, and improved security measures. Even with today's advanced computers and printers, current estimates are that fewer than two out of every 10,000 bills in circulation are counterfeit.⁹

In addition, much attention was given to general deterrence of healthcare providers and beneficiaries through greater criminal sanctions and vastly increased publicity of successful prosecutions. Since the inception of the Strike Force, DOJ has routinely issued press releases highlighting its successes. Numerous national news outlets, including *60 Minutes*, have featured reports on the progress of the Strike Force.

One benefit of the national approach is the ability to have coordinated “take downs”—multiple arrests in various cities around the country on the same day. This technique not only generates public interest and awareness, it motivates investigators and prosecutors to complete investigations by setting a date for charging targets. As noted above, a typical federal investigation progressed at its own pace. Absent a specific danger or need, there was no particularly compelling reason to charge a case in any given time frame. The national coordinated effort gives prosecutor target dates to charge, allowing for more and quicker prosecutions.

Methodology

So how has the relatively small Strike Force been able to have this success in a relatively short amount of time?

Again, the Strike Force adapted tried and true law enforcement methodologies that translated well to the healthcare arena. In the late 1980s, a New York City Transit Police Lieutenant named Jack Maple mapped every robbery in the New York City subway system. By looking at this data, he was able to deploy his officers to “hot spots”; depicting where and when the robberies were occurring. Under his watch, New York City subway robberies related to gangs were reduced from more than 1200 to twelve per year.¹⁰ Maple's system became known as the COMPSTAT (computerized statistics) model, and has been employed by virtually every major police force in the nation.

The vast computerized Medicare data lent itself quite well to real-time analysis. Much like COMPSTAT, the “Strike Force” model relied on such real-time data analysis to identify where, when, and how criminals were defrauding Medicare.

The philosophy was simple: analyze current billing data to find outliers—providers who were billing Medicare such exorbitant amounts that the only legitimate explanation was a fraudulent one. Because the frauds were ongoing and huge sums of money were being extracted from the system, the Strike Force focused on quick prosecutions. In a typical federal prosecution, including healthcare frauds, an investigation could take several months or even years. In a Strike Force case, the idea was to gather enough evidence to prove the defendant's guilt beyond a reasonable doubt, but no more. If the target was engaged in multiple schemes, the Strike Force would concentrate on the easiest one to prove and charge just that one. This technique allowed for quick prosecutions—shortening investigations often from months or years to weeks.

The data comes in many forms including provider claims, cost reports, prescription data, US Securities and Exchange Commission, nonprofit, and UCC filings, among a myriad of other sources. Investigators analyze it in many ways through data

queries, correlations, and trend analysis (by provider type, CPT code, locations, etc.). They perform peer comparisons, statistical sampling, and conduct “impossible days” analyses—where providers billed for more than twenty-four hours of work in one day. They look for double billing and upcoding (billing for a more expensive service when a less expensive one was actually performed). These analyses help determine whether fraud is evident and if an investigation is warranted. The data helps begin the investigation, but as noted below, is by no means the only technique used.

Practice

At first, in Miami, the Strike Force focused on the easiest cases to prove—those that involved outright fraud in two areas, HIV infusion therapy and DME. In fact, in detailing the formation of the Strike Force, DOJ stated that its purpose was “to prosecute individuals and entities that do not provide legitimate health care services, but exist solely for the purpose of defrauding Medicare and other government health care programs.”¹¹

This first wave of prosecutions had a remarkable effect. DME submissions were cut by 63%, and payments went down by 49% during the Strike Force’s first year.¹² More than 100 criminals were convicted (and sentenced to significantly longer prison terms) and tens of millions of dollars were returned to the Medicare trust fund.

These first cases involved “store front” DME sellers; established by fraudsters not to sell DME, but rather bilk Medicare. Often they did not even keep medical supplies on hand in their stores. Many times, the stores weren’t even open. They had been created only to create the illusion of a business.

Quickly, however, as word spread of the Strike Force, criminals changed tactics and locations. They began to move throughout the country and infiltrate other areas of healthcare. No longer were they focused only on sham store fronts, but rather, they mixed fraudulent activity with legitimate medical services such as physical therapy, home health, and other clinical services. Targets and defendants were engaged in all facets of healthcare—doctors, nurses, clinicians, billing companies, and patients.

The Strike Force spread over the next two years to eight additional cities—Los Angeles, Detroit, Houston, Brooklyn, Baton Rouge, Dallas, Chicago, and Tampa. As it entered each city, it noticed that with each new location came a “prevailing” fraud—for example, in Brooklyn, the data suggested that a significant amount of fraud was occurring at physical therapy clinics. The focused strike force model lent itself well to adjust to different fraud schemes. Investigators and prosecutors quickly learned about the new schemes and became expert in their nuances. As schemes changed, so, too, did the investigations.

While the data analysis is critical to identifying potential fraud schemes, it is very rarely, if at all, enough by itself to prove a particular defendant’s guilt beyond a reasonable doubt. As the Strike Forces have expanded, so, too, have their techniques. Recently they have employed many staples of traditional law enforcement to investigate healthcare fraud, such as the use of

cooperating witnesses, handwriting comparisons, undercover operations, and wiretaps with much success. Such techniques are necessary as schemes gain in complexity and involve beneficiaries who are unlikely to cooperate with the investigations.

Over the last year, the Strike Force has begun to take on even more complex and diverse fraud schemes in an effort to not just catch the slow and the stupid criminals, but the smart and swift as well.

One example is the recent prosecution of the owners and operators of a community mental health center, American Therapeutic Corporation (ATC), who over an eight-year period stole more than \$200 million from Medicare by fraudulently operating partial hospitalization programs (PHP) throughout Florida. A PHP is a form of intensive treatment for severe mental illness. The defendants paid bribes and kickbacks to recruit Medicare beneficiaries to attend ATC. They repeatedly billed Medicare for treatments that were medically unnecessary or never provided at all. The defendants concealed their fraud through an extensive and complex money laundering scheme. They paid kickbacks to owners and operators of assisted living facilities and halfway houses in exchange for the delivery of ineligible patients to their PHPs. In some instances the patients were paid kickbacks as well.¹³ The owners were recently sentenced to fifty and thirty-five years in prison, respectively. These sentences were the longest ever imposed for a healthcare crime in the nation.

In another case, eight employees, doctors, and owners of Bay Medical Care in Brooklyn, NY, were charged with thousands of kickbacks to Medicare beneficiaries to encourage them to repeatedly return for unnecessary physical therapy, resulting in \$70 million stolen from Medicare. The investigation of Bay Medical included an undercover officer posing as a Medicare beneficiary, allowing law enforcement to place a court-ordered video wiretap in Bay Medical’s “Kickback Room,” where employees and owners handed beneficiaries thousands of dollars in kickbacks.¹⁴ This is believed to be the first time a video wiretap was used in a healthcare fraud prosecution in the nation.

A third example shows how the Strike Force is consistently expanding the types of fraud it investigates and prosecutes. This past summer, two pharmacists who owned and operated Monica’s Pharmacy and L&A Pharmacy, two “Mom and Pop” drugstores in Brooklyn, NY, were charged with conspiracy to commit healthcare fraud by defrauding the Medicare Part D prescription drug program. The two pharmacists repeatedly billed Part D for prescription medications that they never purchased from pharmaceutical manufacturers or distributors and that they never dispensed to Medicare beneficiaries. The defendants submitted claims for more than 869,000 units of prescription medication without the existence of any sales invoices, resulting in approximately \$3 million in false and fraudulent claims paid by Part D.¹⁵ This is believed to be the first Part D fraud prosecution in the nation.

It should be anticipated that the Strike Force will bring more cases like ATC, Bay Medical, and Monica’s in the near future.

Moving Forward

With success thus far, the Medicare Fraud Strike Force is likely to be around for quite some time. Last year, President Barack Obama allocated an additional \$60 million for Strike Force-related activities. By the end of fiscal year 2011, there is a plan to have the Strike Force in an additional eleven cities, bringing the total to twenty.

While the Strike Force may exist in perpetuity, its success also has encouraged various U.S. Attorney offices to commit vital local resources to healthcare fraud prosecutions—Miami and Detroit being two excellent examples. These permanent positions will further enhance healthcare fraud prosecutions by: (1) freeing up Strike Force prosecutors and investigators to move on to new locations, and (2) allowing Assistant U.S. Attorneys in the local offices to gain expertise in handling these increasingly complex crimes.

Conclusion

The last four and a half years have seen a meteoric rise in healthcare fraud prosecutions around the country, primarily due to the Medicare Fraud Strike Force. Its ability to blend investigative and prosecutorial techniques, act quickly and decisively, and dismantle ever changing fraud schemes has created a model that is not only likely to be around for many years to come, but also be copied in other industries as well.

- 1 See <http://seniorjournal.com/NEWS/2000%20Files/Aug%2000/FTR-08-04-00MedCarHisty.htm>.
- 2 See www.statehealthfacts.org/comparemaptable.jsp?yr=200&styp=1&ind=290&cat=6&sub=74&sortc=1&ro=a.
- 3 See www.statehealthfacts.org/comparemaptable.jsp?ind=933&cat=8.
- 4 See www.kff.org/medicare/upload/7305-05.pdf.
- 5 See www.smpresource.org/Content/NavigationMenu/AboutSMPs/Medicare-FraudEstimatesAMovingTarget/Medicare_Fraud_Estimates.pdf.
- 6 See www.universityofcalifornia.edu/senate/reports/hccosts.pdf.
- 7 See www.kff.org/insurance/snapshot/OECD042111.cfm.
- 8 See www.secretservice.gov/money_technologies.shtml.
- 9 See www.libraryindex.com/pages/496/White-Collar-Crime-FORGERY-COUNTERFEITING.html.
- 10 See www.jrrobertssecurity.com/articles/environmental-criminology.htm.
- 11 See www.stopmedicarefraud.gov/heatsuccess/heat_taskforce_miami.pdf.
- 12 *Id.*
- 13 See www.justice.gov/opa/pr/2011/April/11-crm-480.html.
- 14 See www.justice.gov/usao/nye/pr/2010/2010jul16.html.
- 15 See www.justice.gov/opa/pr/2011/July/11-crm-970.html.

Practice Groups Staff

Trinita Robinson

Vice President of Practice Groups
(202) 833-6943
trobinson@healthlawyers.org

Magdalena Wencel

Senior Manager of Practice Groups
(202) 833-0769
mwencel@healthlawyers.org

Denis Vidal

Practice Groups Administrator
(202) 833-0782
dvidal@healthlawyers.org

Crystal Taylor

Practice Groups Coordinator
(202) 833-0763
ctaylor@healthlawyers.org

Brian Davis

Practice Groups Editorial Coordinator
(202) 833-6951
bdavis@healthlawyers.org

Ramon Ramirez

Practice Groups Coordinator
(202) 833-0761
rramirez@healthlawyers.org

Tazeen Dhanani

Practice Groups Web Assistant
(202) 833-0840
tdhanani@healthlawyers.org

Graphic Design Staff

Mary Boutsikaris

Creative Director
(202) 833-0764
mboutsik@healthlawyers.org

Ana Tobin

Graphics Assistant
(202) 833-0781
atobin@healthlawyers.org

Darned If You Do and Darned If You Don't: Perspectives on the Benefits and Dangers of the CMS Self-Referral Disclosure Protocol*

Rebecca A. Matthews, Esquire

Jody Erdfarb, Esquire

Wiggin & Dana LLP

New Haven and Stamford, CT

More than a year ago, on September 23, 2010, the Centers for Medicare & Medicaid Services (CMS) published the Self-Referral Disclosure Protocol (SRDP) that it developed in response to the Patient Protection and Affordable Care Act (PPACA) mandate that the U.S. Department of Health and Human Services (HHS) establish a protocol for the disclosure and resolution of violations of the Physician Self-Referral Law, more commonly known as Stark.¹ Because disclosure under the protocol is voluntary, since its release, providers have struggled with deciding whether or not to disclose pursuant to the SRDP.

To date, there has been only one publicized SRDP settlement: on February 10, 2011, Saints Medical Center in Lowell, MA, announced that it agreed to pay \$579,000 to resolve its Stark liability. Saints stated that this amount was “less than the reserve . . . set aside . . . to address this issue, which was based on management’s estimate of the low end of the range of the potential obligation.”² According to a local newspaper, Saints Medical Centers’ potential liability was \$14 million,³ indicating that participation in the SRDP may be a favorable alternative for providers.

On April 7, 2011, CMS announced that it was processing sixty disclosures pursuant to the SRDP.⁴ As more of these cases are resolved, further information will become available regarding CMS’ efforts to resolve Stark liability in a flexible, collaborative manner through use of the protocol. Until then, as providers review their physician relationships and consider disclosure under the SRDP, they should carefully evaluate the potential benefits and dangers outlined in the protocol.

The Stark Law

Stark prohibits a physician from making referrals for certain designated health services (DHS), payable by Medicare or Medicaid, to an entity with which he or she has a financial relationship, unless an exception applies. Because Stark is a strict liability law, its penalties may be imposed even for technical violations, including common mistakes such as failure to renew an expired contract. Penalties can be severe and may require a refund of all payments made for DHS referred by the physician while the relationship was not in compliance with Stark, plus penalties and interest. For example:

- In March 2010, after a seven-year, whistleblower-initiated investigation, Rush University Medical Center in Chicago

agreed to pay \$1.5 million plus interest to resolve allegations that the facility violated Stark by entering into certain leasing arrangements for office space with physicians.⁵

- In November 2010, Saint Joseph’s Medical Center in Towson, MD, agreed to pay \$22 million to settle allegations that it violated the Anti-Kickback Statute and Stark when it entered into a series of professional services contracts with a cardiology group. The payments under these contracts were allegedly higher than fair market value and for services not rendered or that were not commercially reasonable.⁶
- In December 2010, Detroit Medical Center agreed to pay \$30 million to resolve allegations involving improper financial relationships with referring physicians. According to the U.S. Department of Justice, “most of the relationships at issue . . . involved office lease agreements and independent contractor relationships that were either inconsistent with fair market value or not memorialized in writing.”⁷

The SRDP

The SRDP is intended to facilitate the resolution of actual and potential Stark violations. According to CMS, a disclosing party should only make a submission pursuant to the SRDP with the intention of resolving its Medicare overpayment liability exposure. PPACA granted the HHS Secretary the authority to reduce the amount “due and owing” for all Stark violations and in the protocol, CMS stated that it will “work closely with a disclosing party that structures its disclosure in accordance with the SRDP to reach an effective and appropriate resolution.”⁸

While the SRDP can serve as a helpful tool in resolving potential Stark liability, before taking advantage of the SRDP, healthcare providers should carefully consider the various factors outlined here when determining whether to disclose under the SRDP.

Eligibility

Participation in the SRDP is limited to actual or potential Stark violations. If the disclosure includes violations of other laws, such as the Anti-Kickback Statute, which is enforced by the Office of Inspector General (OIG), the SRDP cannot be used. The OIG Self Disclosure Protocol, which has been in place since 1999, should be considered in such instances.⁹ Because the SRDP and the OIG Self Disclosure Protocol cannot be used simultaneously, providers must carefully consider the proper avenue for disclosure.

Also, the SRDP cannot be used to obtain an advisory opinion as to whether certain circumstances violate Stark. According to CMS, if a disclosing party argues that the circumstances do not constitute a Stark violation, the disclosure will not be accepted into the SRDP. In addition, providers may not disclose through the SRDP and request an advisory opinion regarding the same arrangement concurrently. Therefore, providers must have concluded that a Stark violation occurred and should be prepared to enter a corresponding monetary settlement before disclosing pursuant to the SRDP.

Interestingly, a disclosing party that is already subject to government inquiry through investigations, audits, or routine oversight may still avail itself of the SRDP, so long as the disclosure is made

in good faith. In addition, providers that are under Certification of Compliance Agreement (CCA) or Corporate Integrity Agreement (CIA) reporting obligations must disclose reportable events solely related to a Stark issue pursuant to the SRDP, with a copy to the disclosing party's OIG monitor.

Benefits

Suspension of the Sixty-Day Reporting and Repayment Obligation

An initial immediate benefit to disclosing pursuant to the SRDP is that the submission of a disclosure suspends the obligation, under Section 6402 of PPACA, to return overpayments within sixty days of identification. This suspension of the sixty-day timeframe lasts until a settlement agreement is entered or the disclosing party withdraws from the SRDP or is removed from the SRDP by CMS.

Damages Calculation

In theory, the primary benefits of self-disclosure pursuant to the SRDP are that the provider can resolve the violation, potentially pay reduced monetary amounts, and avoid a costly government investigation. The SRDP provides the opportunity to disclose and enter a monetary settlement in order to avoid the risk of investigation and prosecution to the fullest extent of the law. PPACA, for the first time, provided CMS with the authority to reduce the amount owed, based on the following factors:

- Nature and extent of the illegal practice;
- Timeliness of the self-disclosure;
- Cooperation in providing additional information related to the disclosure;
- Litigation risk associated with the matter disclosed; and
- The financial position of the disclosing party.

CMS additionally stated that it will consider the following sub-factors:

- Agreement's commercial reasonableness;
- Whether the agreement took into account the value or volume of referrals;
- Whether the agreement's compensation terms were set in advance;
- Length and pervasiveness of the noncompliance;
- Steps taken to correct the noncompliance;
- Whether the provider has a history of program abuse;
- Presence and strength of the provider's compliance program;
- Timeliness of the self-disclosure;
- Provider's cooperation in providing additional information; and
- Disclosing party's financial position.

These factors may operate for the benefit or to the detriment of the provider, depending on the circumstances. The SRDP does not set forth any formula or set methodology, and CMS has no obligation to reduce any overpayment amounts identified. Individual determinations will be made based on facts and circumstances.

CMS stated that it does not intend to issue press releases or otherwise publicize particular SRDP settlements; rather, it will leave the decision about whether or not to publicize to the disclosing party.¹⁰ The Saints' Medical Center settlement, described above, became public via a press release issued by the Hospital. That settlement is the only publicized settlement reached via the SRDP thus far and seemed very favorable to the provider.

In March 2012, CMS must submit a report to Congress on the SRDP detailing the number of settled self-disclosures, the amounts collected, and other data. Until then, other than anecdotal settlements that may become public, providers will likely have little precedent or other guidance to predict how their cases may be resolved, causing the greatest potential benefit of the SRDP to also be one of its greatest potential dangers.

Dangers

Further Investigation

As explained above, the SRDP is to be used only for potential or actual Stark violations and not in cases where other laws may be implicated, such as the Anti-Kickback Statute. CMS makes it clear that once a disclosure is made, whether or not it is accepted into the SRDP, CMS may refer the case to OIG and the Department of Justice (DOJ) for resolution under the False Claims Act, civil monetary penalty, or other liability. Therefore, CMS warns that "the disclosing party's initial decision of where to refer a matter involving non-compliance with . . . [Stark] should be made carefully."¹¹ Moreover, CMS states that if it uncovers matters during its verification process that are outside the scope of the matter disclosed, CMS may treat them as new matters outside the SRDP, subject to separate investigation by the appropriate authorities.

Period of Disallowance

The disclosing party is required to conduct a financial analysis of its Stark liabilities and disclose its findings to CMS. The financial analysis must set forth the total amount, itemized by year, that is actually or potentially "due or owing." Generally, this calculation will include all Medicare payments for DHS received by the disclosing party that were made as a result of referrals generated while the relationship was not Stark compliant. The calculation must cover the entire time period "during which the disclosing party may not have been in compliance with the physician self-referral law." When the disclosure involves longstanding arrangements, this period could cover many years and even go further back than the general four-year period in which CMS may reopen claims for good cause. Although CMS representatives publicly stated¹² that they need to analyze the amounts paid over the entire period of noncompliance in order to fully understand the scope of the violations involved, providing a financial analysis for that entire time period will prove challenging for some providers and also might make it difficult for providers to negotiate smaller settlements.

Forfeiture of Right to Appeal

As a condition of disclosing a matter pursuant to the SRDP, the disclosing party must agree that no appeal rights attach to claims relating to the conduct disclosed if resolved through a settle-

ment agreement. The forfeiture of appeal rights occurs only if a settlement is reached. If the party stops participating in the SRDP process at any point, by either withdrawing or by being removed by CMS, then the party may appeal any subsequent government action as appropriate.

Forfeiture of Attorney-Client Privilege

In the course of its verification of the disclosure, CMS may require access to all financial statements, notes, disclosures, and other supporting documents without the assertion of privileges or limitations on the information produced. While CMS states that it will not specifically request the production of written communications that are subject to attorney-client privilege, it further explains that it may demand to see documents or other materials covered by the work product doctrine when CMS believes the document will be critical to resolving the disclosure. In those instances, according to the SRDP, CMS will work with the disclosing party's counsel on ways to gain access to that information without the need for a waiver of the attorney-client privilege.

Cooperation

The decision to enter the SRDP is only the beginning. Providers must be meticulous in ensuring that all submissions are accurate and complete. All submissions must be accompanied by a certification stating that the information is truthful and is based on a good-faith effort to bring the matter to CMS' attention to resolve any potential liabilities. According to CMS, "the intentional submission of false or otherwise untruthful information, as well as the intentional omission of relevant information, will be referred to DOJ or other Federal agencies and could, in itself, result in criminal and/or civil sanctions, as well as exclusion from participation in Federal health care programs."¹³ Also, providers must be prepared to cooperate fully with CMS' verification of the disclosure, including providing additional information. CMS stated it is "essential" to show "diligent and good faith cooperation throughout the entire process."¹⁴ A perceived lack of cooperation could result in CMS' removal of the case from the SRDP and referral to other government authorities.

Reopening

As a condition of entering the SRDP, providers must agree that if they are denied acceptance in the SRDP, withdraw from the SRDP, or are removed from the SRDP by CMS, the reopening rules at 42 CFR 405.980 through 405.986, which allow government contractors to reopen claims after a binding payment decision has already been made, apply from the date of the initial disclosure to CMS. This is significant because it means that by virtue of the disclosure, the provider is essentially allowing CMS to re-examine paid claims that would otherwise be closed. Note, however, that in a fraud investigation, the government may reopen a claim at any time if there exists reliable evidence that the initial payment determination was procured by fraud or similar fault.

Conclusion

The SRDP can be effective if used appropriately. In cases where a provider is aware of an overpayment due to Stark noncompliance

and where no other laws are implicated, the SRDP is an attractive option as it may result in reduction of the overpayment and will, at the very least, result in resolution of the matter with HHS. Use of the SRDP can also be disastrous, however, if the provider is oblivious to its potential dangers. Providers must not only ensure that their cases are eligible for submission to the SRDP, but also analyze the unique facts and circumstances involved and conduct a thorough risk-benefit analysis before proceeding.

Simply put, the SRDP might cause providers to feel stuck in a "damned if you do, darned if you don't" quagmire. Although proceeding with the SRDP has inherent dangers, failing to disclose potential Stark liability may put a provider in significant jeopardy as well. As more information, particularly about specific SRDP settlements, is released, hopefully, providers will feel more comfortable taking advantage of the benefits the SRDP is intended to provide.

Note: After this article was submitted, a new SRDP settlement was posted on the CMS website. According to CMS: "On November 11, 2011, CMS settled several violations of the physician self-referral statute disclosed by a critical access hospital located in Mississippi (Hospital) under the SRDP. The Hospital disclosed under the SRDP that it violated the physician self-referral statute by failing to satisfy the requirements of the personal services arrangements exception for arrangements with certain hospital and emergency room physicians. All violations disclosed were settled for \$130,000.00.

Also note that a version of this article was originally published in the May 16, 2011, Vol. 37, No. 20 issue of the Connecticut Law Tribune.

- 1 The CMS SRDP is available at www.cms.gov/PhysicianSelfReferral/Downloads/6409_SRD_Protocol.pdf.
- 2 See www.saintsmedicalcenter.com/news/CMS/.
- 3 Nina Youngstrom, First Stark Case Is Resolved Through CMS Self-Disclosure; Is the OIG Option Gone?, AISHealth, February 21, 2011, available at <http://aishealth.com/archive/rmc022111-02>.
- 4 The New Stark Self-Disclosure Protocol: A New Solution, The American Bar Association Health Law Section and the ABA Center for Continuing Legal Education Teleconference, April 7, 2011.
- 5 See www.justice.gov/opa/pr/2010/March/10-civ-240.html.
- 6 See www.justice.gov/opa/pr/2010/November/10-civ-1271.html.
- 7 See www.justice.gov/opa/pr/2010/December/10-civ-1484.html.
- 8 CMS Voluntary Self-Referral Disclosure Protocol, OMB Control Number: 0938-1106, at page 2. The CMS SRDP is available at www.cms.gov/physicianselfreferral/downloads/6409_srdp_protocol.pdf.
- 9 The OIG Self Disclosure Protocol is available at <http://oig.hhs.gov/authorities/docs/selfdisclosure.pdf>.
- 10 The New Stark Self-Disclosure Protocol: A New Solution, The American Bar Association Health Law Section and the ABA Center for Continuing Legal Education Teleconference, April 7, 2011.
- 11 CMS Voluntary Self-Referral Disclosure Protocol, OMB Control Number: 0938-1106, at page 3. The CMS SRDP is available at https://www.cms.gov/physicianselfreferral/downloads/6409_srdp_protocol.pdf.
- 12 Stark Self Disclosure: Understanding and Working with CMS's New Self Referral Disclosure Protocol: A Conversation with the Regulators, Health Care Compliance Association Teleconference, January 2011; The New Stark Self-Disclosure Protocol: A New Solution, The American Bar Association Health Law Section and the ABA Center for Continuing Legal Education Teleconference, April 7, 2011.
- 13 CMS Voluntary Self-Referral Disclosure Protocol, OMB Control Number: 0938-1106, at page 6. The CMS SRDP is available at www.cms.gov/physicianselfreferral/downloads/6409_srdp_protocol.pdf.
- 14 *Id.*

Turning a Blind Eye to Overpayments: Not Worth the Gamble

Barbara J. Zabawa, JD, MPH, FACHE
Whyte Hirschboeck Dudek SC
Madison, WI

“First do no harm” seems like an impossible feat in today’s increasingly complicated health environment. The difficulty is as true for the delivery of care as it is for billing for the care provided. The United States health environment is one in which flawless performance is a constant challenge.

On September 27, 2011, the Health Law Team of Whyte Hirschboeck Dudek SC, in partnership with the University of Wisconsin Law School, hosted a Health Care Happenings conference to help healthcare stakeholders tackle this sobering reality. Federal and state regulators, healthcare providers, and insurers convened in Madison, WI, to discuss, among other topics, what to do when a provider discovers overpayments from federal or state government coffers.

The panel that confronted this topic, moderated by the author, consisted of a Medicare Carrier representative, an assistant U.S. Attorney (AUSA) from the Western District of Wisconsin, and the director of the Wisconsin Medicaid Fraud Control Unit. In response to a series of hypotheticals involving a self-discovered overpayment of \$3 million, several underlying messages emerged.

Key Messages From the Government

First, voluntary disclosures of overpayments help, but they are not a panacea to further government involvement.

According to the Medicare Carrier representative, just because a healthcare provider voluntarily reports an overpayment, such disclosure does not foreclose the possibility of further investigation and prosecution. Under the Centers for Medicare & Medicaid Services (CMS) Manual, “[t]he acceptance of a voluntary refund as repayment for the claims specified in no way affects or limits the rights of the Federal Government, or any of its agencies or agents, to pursue any appropriate criminal, civil, or administrative remedies arising from or relating to these or any other claims.”¹

According to the Medicare Carrier representative, very large overpayments will attract the attention of the government and likely result in a referral to the U.S. Attorney’s office. This is because larger payments can indicate to the U.S. Attorney’s office that the overpayments were intentional.

Once the U.S. Attorney gets involved, the amount at stake and criminal intent become key factors. Other factors that the U.S. Attorney’s office considers when deciding whether to pursue the case are: (1) the nature and seriousness of the offense; (2) the pervasiveness of the problem; (3) whether the healthcare

provider self-disclosed the wrongdoing; (4) the healthcare provider’s willingness to cooperate; (5) whether the provider has a compliance program; (6) any potential collateral consequences of prosecution (such as adverse impact on patients); (7) adequacy of prosecutions of individuals; and (8) adequacy of civil or other regulatory remedies.

These federal prosecution factors from the U.S. Attorney’s Manual help the U.S. Attorney’s office determine whether pursuing an action against a provider is worth dipping into the limited resources available to the office. The AUSA noted that his office does not have enough time to prosecute everything. However, that does not mean an investigation is over. Other federal agencies may continue looking into the matter, such as the Federal Bureau of Investigation or the U.S. Department of Health and Human Services, Office of Inspector General (OIG).

The Wisconsin Medicaid Fraud Control Unit (MFCU) works with the U.S. Attorney’s office regularly to respond to referrals from both state and federal agencies concerning Medicaid overpayments. The mission of the Wisconsin MFCU is to protect the assets of the Wisconsin Medicaid program, as well as protect Medicaid recipients from abuse and neglect. To help protect Medicaid assets, the Wisconsin MFCU has healthcare task forces in the Eastern and Western Districts of Wisconsin. These task forces discuss prosecutions, theories of liability, and healthcare industry trends. In addition, the Wisconsin MFCU informally follows the federal prosecution factors used by the U.S. Attorney’s office, identified above, when deciding whether to prosecute a provider.

A second message from the panelists was that implementing compliance programs is essential.

All three panelists stressed the importance of compliance programs and self-audits. As noted by the AUSA, healthcare providers can mitigate criminal intent and at least avoid a criminal prosecution by instituting a compliance program and conducting self-audits. By following a compliance program and reporting an overpayment, the provider undermines the criminal intent element essential for an AUSA or the Wisconsin MFCU to prosecute a case as criminal. The AUSA panelist pointed out that although civil prosecutors might still be interested in the case, no one would be going to jail. The AUSA recognized that mistakes happen. He commented that his office is sensitive to the fact that criminal charges against an entity are devastating and have very serious repercussions to providers. He explained that the federal prosecution factors help federal prosecutors maintain that sensitivity. Defense lawyers who are aware of those factors will be better equipped when negotiating with U.S. Attorneys’ offices.

The Medicare Carrier representative noted that corporate compliance efforts are critical to the carrier’s response. Carriers will react more positively to providers who make efforts to return overpayments and such efforts may influence the carrier’s decision whether it should refer the case to the U.S. Attorney’s office. The carrier looks at patterns, types, and amounts of overpayments when determining next steps. Self-disclosing the overpayments mitigates the need for further action by the carrier.

A third message from all three panelists was that concealing an overpayment is a very bad idea.

The Wisconsin MFCU highlighted that the Wisconsin Department of Health Services, which administers the Medicaid program, has auditors within its Bureau of Program Integrity. These auditors are in addition to the persons and entities that audit the Medicare program, such as Recovery Audit Contractors. The Wisconsin MFCU director stated that if a provider fails to report an overpayment, someone else will. At that point the overpayment will become a much more serious problem. That is because, as explained by the AUSA, several federal statutes make concealing information about federal healthcare payments a criminal act. For example, under 18 U.S.C. Section 1035:

- (a) Whoever, in any matter involving a health care benefit program, knowingly and willfully –
 - (1) falsifies, **conceals**, or covers up by any trick, scheme, or device a material fact; or
 - (2) makes any materially false, fictitious, or fraudulent statements or representations, or makes or uses any materially false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry,

in connection with the delivery of or payment for health care benefits, items, or services, shall be fined under this title or imprisoned not more than 5 years, or both.²

Other laws cited by the AUSA that the U.S. Attorney's office may use to criminalize the concealment of overpayments include 18 U.S.C. Section 24(b), 42 U.S.C. Section 1320a-7b(3), 18 U.S.C. Section 1516(a), 18 U.S.C. Section 1518(a), and 18 U.S.C. Section 4.

Moreover, the Medicare Carrier representative revealed that once a carrier determines an overpayment has been made, it must attempt recovery of that overpayment pursuant to CMS Manual 100-6, Medicare Financial Management Manual, Ch. 3, Section 10 (stating that "once an intermediary or carrier determines and overpayment has been made it must attempt recovery of overpayments in accordance with CMS regulations"). The Manual continues by stating:

The Federal Claims Collection Act requires timely and aggressive efforts to recover overpayments, including efforts to locate the debtor where necessary, demands for repayment, and establishment of repayment schedules, suspension of interim payments by intermediaries to institutional providers, and recoupment or setoff, where appropriate.

In addition, the Debt Collection Improvement Act of 1996 requires Federal agencies to refer eligible delinquent debt to a Treasury designated Debt Collection Center (DCC) for cross servicing and offset. CMS is mandated to refer all eligible debt over 180 days delinquent for cross servicing and offset.³

Consequently, failing to report overpayments triggers the Carrier's obligation to recover the payment through a variety of means, including the involvement of other federal agencies like the Treasury Department.

These three messages revealed at the Health Care Happenings Conference are not necessarily novel, but they are important for providers to consider as they continue to operate in an increasingly complicated regulatory environment. As pointed out by the panelists, both state and federal governments are tightening enforcement efforts and pouring more resources into state and federal audit programs. These enhanced auditing capabilities make it more likely that the government will discover an overpayment. As a result, successfully concealing an overpayment is becoming less and less plausible. More importantly, concealing overpayments subjects the provider to criminal liability, even if the original overpayment was a mere mistake. It is imperative that healthcare providers steer clear of criminal sanctions, as such sanctions can subject them to federal and state healthcare program exclusion, *see e.g.*, 42 U.S.C. Section 1320a-7, in addition to financial penalties, imprisonment, and an adverse impact on the provider's reputation in the community.

Despite these harsh realities, there are several action items healthcare providers can do right now to minimize the risk of federal or state government regulators.

Healthcare Provider Action Items

Institute a Compliance Program

If a healthcare provider has not done so already, it should establish a compliance program to guide its employees on what the government expects of the provider. Having a compliance program is one of the federal prosecution factors considered by AUSAs and state prosecutors when deciding whether to pursue a case. OIG has published numerous compliance program guides for a variety of healthcare provider types, such as hospitals, nursing facilities, physician practices, ambulance suppliers, DMEPOS suppliers, clinical laboratories, home health agencies, third-party medical billing companies, and hospices. These compliance program guides can be downloaded at <http://oig.hhs.gov/compliance/compliance-guidance/index.asp>. Providers should work with their legal counsel in establishing such programs.

Implement the Compliance Program

It is not enough to create a healthcare compliance program and then set it on a shelf to collect dust. The government regulators at the conference stressed the importance of providers making

efforts to comply when deciding whether to take further action. Efforts include conducting self-audits and correcting discovered errors in billing, coding, and other procedures. A healthcare provider should consider hiring legal counsel to coordinate a self-audit so that results of the audit can be discussed under the attorney-client privilege.

Consult Legal Counsel When Overpayments Are Found

Upon discovering an overpayment, a healthcare provider should first consult its legal counsel before rushing to disclose the overpayment to the government. Good legal counsel can help shape a response to the government that will minimize risk associated with the disclosure. In addition, legal counsel can assist the healthcare provider in determining which governmental entity is best for the disclosure. As discussed by the Health Care Happenings conference panel, numerous entities have jurisdiction over Medicare and Medicaid. Often, legal counsel will consider relationships he or she has with various federal and state regulators. It is important for healthcare providers to consider the strength of these relationships when choosing legal counsel. Local counsel may have a better rapport with local regulators compared with counsel who are less familiar with the local healthcare market.

Conclusion

There is no shortage of regulatory concerns for healthcare clients. The United States' patchwork system of payments creates numerous opportunities for billing, coding, and documentation mistakes. The regulatory environment places healthcare providers in a difficult position to deliver high-quality, efficient care because of the morass of rules from a multitude of federal and state agencies. It is no easy task to fulfill a mission to serve the community and provide high-quality care to patients within the strict confines of compliance expectations. Health lawyers who specialize in fraud and abuse can ease providers' compliance burden by identifying manageable tasks and documenting compliance efforts for future reference. Those lawyers are also essential when problems arise because they can help the provider manage the crisis and respond to government inquiries effectively.

1 CMS Manual 100-6, Ch. 5, Financial Reporting, § 410.10.

2 18 U.S.C. § 1035(a) (emphasis added).

3 CMS Manual 100-6, Ch. 3, § 10.

Fraud and Abuse Practice Group Leadership

Mark A. Bonanno Chair

Law Offices of Mark Bonanno LLC
Portland, OR
(503) 493-3330
mab@healthlawoffice.com



William Mathias, Vice Chair – Strategic Activities

Ober|Kaler
Baltimore, MD
(410) 347-7667
wmathias@ober.com



Gary W. Herschman, Vice Chair – Research & Website

Sills Cummis & Gross PC
Newark, NJ
(973) 643-5783
gherschman@sillscummis.com



Heather M. O'Shea, Vice Chair – Membership

Jones Day
Chicago, IL
(312) 269-4009
hoshea@jonesday.com



Laura Laemmle-Weidenfeld, Vice Chair – Publications

Patton Boggs LLP
Washington, DC
(202) 457-6542
llaemmleweidenfeld@pattonboggs.com



Carol A. Poindexter, Vice Chair – Educational Programs

Shook Hardy & Bacon LLP
Kansas City, MO
(816) 474-6550
cpoindexter@shb.com



Dr. Scott Harkonen, Former CEO of InterMune, Appeals His Criminal Conviction and Exclusion by OIG

*Laurence J. Freedman, Esquire
Cordell A. Hull, Esquire
Patton Boggs LLP
Washington, DC*

On August 31, 2011, the U.S. Department of Health and Human Services, Office of Inspector General (OIG) notified Dr. Scott Harkonen, former chief executive officer (CEO) of InterMune, of his exclusion from all federal healthcare programs for five years. Harkonen, a medical doctor, was the CEO of InterMune from February 1998 through June 30, 2003, and a member of InterMune's board of directors from February 1998 through September 2003. OIG based the exclusion on 42 U.S.C. § 1320a-7(a)(3), which provides for exclusion based on a felony conviction that is "in connection with the delivery of a health care item or service." OIG contended that Harkonen's conviction for wire fraud warranted his exclusion, which went into effect twenty days after the August 31 notice. Harkonen appealed his exclusion on October 30, 2011, requesting a hearing before an administrative law judge (ALJ). OIG refused to stay the exclusion pending the outcome of Harkonen's appeal of his conviction before the Ninth Circuit.

As background, in October 2006, InterMune agreed to enter into a deferred prosecution agreement and to pay nearly \$37 million to resolve criminal charges and civil liability in connection with the illegal promotion and marketing of Actimmune. The company also entered into a five-year Corporate Integrity Agreement with OIG, which expired on October 25, 2011. The U.S. Food and Drug Administration had approved Actimmune for two rare diseases, chronic granulomatous disease and severe, malignant osteopetrosis. Despite its limited indications, physicians were free to prescribe Actimmune for any disease for which they deemed it clinically appropriate.

Harkonen was indicted on March 18, 2008, on one count of wire fraud, in violation of 18 U.S.C. § 1343, and one count of misbranding, in violation of 21 U.S.C. §§ 331(k), 333(a)(2), and 352(a). The wire fraud count was based on Harkonen's approval of a single press release in August 2002 regarding the use of Actimmune for idiopathic pulmonary fibrosis (IPF), a scarring of the lungs that can be fatal, which was not an approved use.

Specifically, the United States alleged that the press release "contained false and misleading information regarding Actimmune and falsely portrayed the results [of a clinical study] as establishing that Actimmune helped IPF patients live longer." The only statements specifically alleged to be false was the headline, which stated, "InterMune Announces Phase III Data Demonstrating Survival Benefit of Actimmune in IPF," and the

subheading, "Reduces Mortality by 70% in Patients with Mild to Moderate Disease." These statements were allegedly made "to induce doctors to prescribe, and patients to take, Actimmune to treat IPF." In September 2009, Harkonen was convicted of the wire fraud count but acquitted of the "misbranding" charge.

At sentencing, the government claimed that the Press Release caused an "actual loss" of \$22,500,000, and an intended loss of \$32,100,000. The government's theory was that any increase in Actimmune prescriptions after August 2002 was caused by the false statements. The government asked the district court to imprison Harkonen for ten years and fine him \$1 million. The district court criticized the government for its "impressionistic" causation theories and said that it was "awfully hard to parse out a loss" because "some people did apparently derive some benefit from" Actimmune. Eventually, the government conceded that it had no evidence that any doctor prescribed Actimmune because of the allegedly false statements. The district court observed that "we can't even figure out who a victim is in this case, and whether the victims were benefited in some way at all or not," and that "there may be other ways of handling violations of this nature besides through criminal charges."

The court instead sentenced Harkonen to three years of probation, 200 hours community service, a \$20,000 fine, and six months home detention (the latter to be served only if the appeal is unsuccessful). On April 25 and June 8, 2011, Harkonen filed notices of his appeal of the district court's decisions denying him a judgment of acquittal or a new trial. Harkonen's counsel has noted that neither Harkonen nor InterMune was ever charged with falsifying the data from the clinical trials. Rather, Harkonen was prosecuted for the conclusions he drew from data accurately reported in the press release. Harkonen maintains that medical researchers have the constitutional right to draw conclusions from accurately reported data, even if the government disagrees with those conclusions. The United States cross-appealed.

In his opening brief on appeal to the Ninth Circuit, filed on October 28, 2011, Harkonen argues that the wire fraud statute does not extend to statements about the medical import of clinical study results; the First and Fifth Amendments protect the expression of scientific opinions and bar the prosecution; and that the government failed to prove knowledge of falsity, the intent to defraud, and the materiality of the statements, all required elements under the wire fraud statute. The United States' response and its opening brief on its cross appeal were due on November 28, 2011, and briefing in the appeal should be complete by mid-January 2012.

In his appeal of the exclusion and request for a hearing before an ALJ, filed on October 28, 2011, Harkonen submits that OIG has no basis upon which to exclude Harkonen. Specifically, he contends that 42 U.S.C. § 1320a-7(a)(3) does not authorize Harkonen's exclusion because his conviction is not connected with the delivery of a healthcare item or service or an act or omission in a healthcare program. Harkonen also argues that his exclusion violates his Fifth Amendment rights to due process and to be free of double jeopardy and his Eighth Amendment right to be free of disproportionate financial punishment.

This exclusion of Harkonen follows the exclusion of three former Purdue Pharma executives, who were excluded by the OIG for twelve years after each being convicted in 2007 of criminal misdemeanors under the “responsible corporate officer” doctrine of criminal misdemeanors. On October 19, 2011, the executives (the former CEO, general counsel, and chief medical officer) filed their reply brief in the District of Columbia Circuit challenging the December 2010 district court order upholding the exclusion imposed by OIG. The executives and the United States disagree over whether the Purdue executives were convicted on excludable offenses, whether OIG applied the exclusion statute correctly, and whether the debarments raise Constitutional concerns. Oral argument before a three-judge panel of the D.C. Circuit is scheduled for December 6.

These exclusion actions are in the context of the OIG-expressed interest in imposing its exclusion authorities, both in the mandatory and permissible exclusion settings. On April 12, 2011, OIG notified the CEO of Forest Laboratories that it sought to exclude him from participation in federal healthcare programs under 42 U.S.C. § 1320a-7(b)(15)(ii), which permits OIG to exclude “officers” and “managing employees” of a “sanctioned entity” without any showing of knowledge by the individual of any alleged wrongdoing—“no fault” or “strict liability” exclusion. On August 5, 2011, OIG notified Mr. Solomon that, after further consideration, it would drop its efforts to exclude him. Also under this “(b)(15)(ii)” authority, OIG previously excluded the former CEO of KV Pharmaceuticals, though he later pleaded guilty to two misdemeanor misbranding charges under the Food, Drug, and Cosmetic Act. OIG in October 20, 2010, issued its “Guidance for Implementing Permissive Exclusion Authority Under Section 1128(b)(15)” and has since expressed its intent to forcefully use this authority.

In the context of FDA regulation of pharmaceuticals and medical devices, the United States, both through the U.S. Department of Justice and OIG, has trumpeted its intent to prosecute more individuals—including prosecutions under the responsible corporate officer doctrine—and to exclude more individuals who are convicted of offenses or who are non-culpable officers or “managing employees” of companies who are “sanctioned entities” by virtue of convictions or exclusions. As this enforcement pressure heats up, courts will grapple with the statutory, First Amendment, Fifth Amendment, and Eighth Amendment issues created by this aggressive enforcement that is unprecedented in the life sciences industry.

Chair’s Two Cents

Mark A. Bonanno, Esquire

*Law Offices of Mark Bonanno LLC
Portland, OR*

Welcome to our inaugural Fraud and Abuse Practice Group (Fraud PG) newsletter. We hope that you enjoy reading the publication, and that you consider volunteering to contribute an article for a future edition.

We value your membership in the Fraud PG. This 2011-2012 term, we have lots to do, including some additional new projects we hope you will find valuable to your practice. Many of you have stepped up to help. We are not able to provide services such as email alerts on fraud and abuse enforcement, Advisory Opinion summaries, the upcoming [Fraud and Abuse Bootcamp Webinar Series](#), timely [Twitter](#) postings, or this newsletter without your volunteer time. So, thank you.

If you have any feedback or want to offer some constructive pointers to your PG leadership, feel free to email any of us below or call me directly at (503) 493-3330.

- Mark Bonanno, Chair
mab@healthlawoffice.com
- Gary Herschman, Vice Chair of Research and Website
gherschman@sillscummis.com
- Laura Laemmle-Weidenfeld, Vice Chair of Publications
lweidenfeld@PattonBoggs.com
- William Mathias, Vice Chair of Strategic Activities
wmathias@ober.com
- Heather O’Shea, Vice Chair of Membership
hoshea@jonesday.com
- Carol Poindexter, Vice Chair of Educational Programs
cpoindexter@shb.com

Fraud and Abuse Practice Group Goes Live on Twitter!

Anthony Choe, Esquire, MPH
Morgan Lewis & Bockius LLP
Washington, DC

Matthew Fisher, Esquire
Mirick O'Connell DeMallie & Lougee LLP
Worcester, MA

Gary Herschman, Esquire
Sills Cummis & Gross PC
Newark, NJ

On November 16, 2011, the Fraud and Abuse Practice Group (Fraud PG) announced the launch of its new Twitter account. The Fraud PG Twitter handle is [@AHLA_FraudAbuse](https://twitter.com/AHLA_FraudAbuse). Through its Twitter feed, the Fraud PG will provide breaking updates about case law, new cases, settlements, enforcement actions, and other regulatory developments within the fraud and abuse sphere of the healthcare industry.

Twitter is a social networking and micro-blogging service that allows for nearly instantaneous communication. The messages, or "tweets," may only be 140 characters or less.

Using Twitter and signing up to track, or "follow," the Fraud PG's updates is quick and easy. The easiest way to follow the feed is to sign up for a Twitter account. You can start one by visiting the [Twitter website](https://twitter.com/AHLA_FraudAbuse). Once you have an account, you simply need to search for AHLA_FraudAbuse, and then click the "Follow" button.

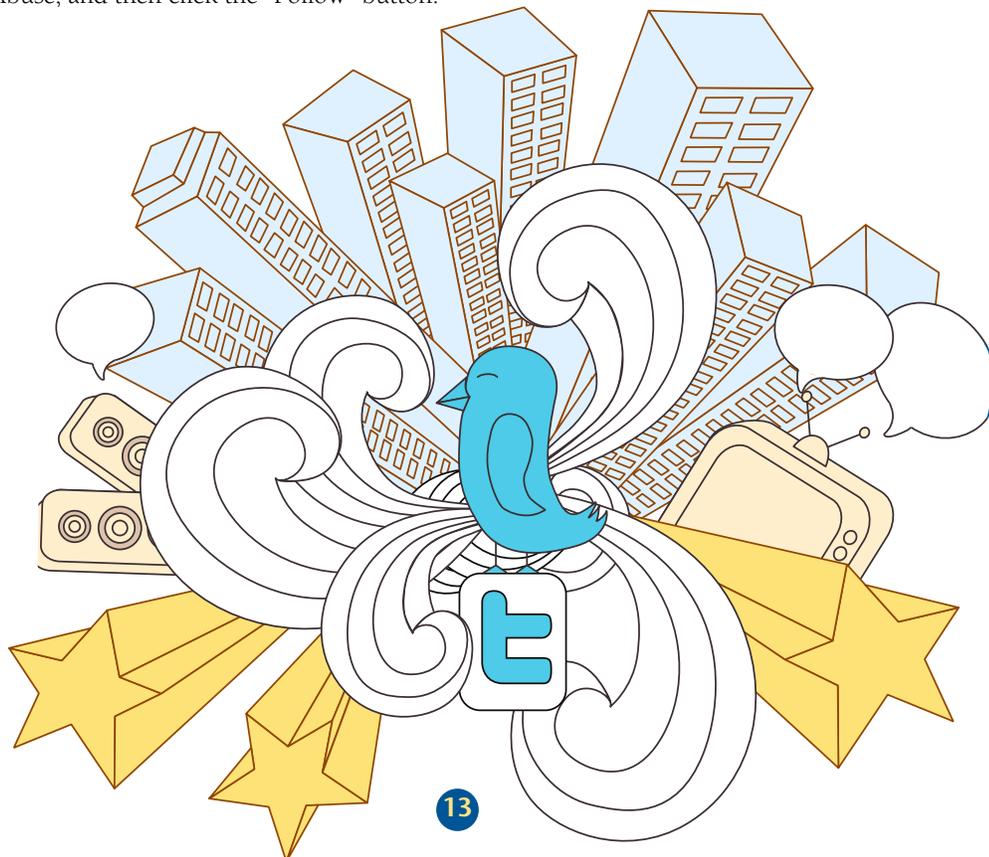
Not sure if you want to sign up for Twitter yet? You can still visit and read the [Fraud PG's feed](https://twitter.com/AHLA_FraudAbuse) while you decide, but you will not be able to reply or tweet on your own.

For those of you who utilize LinkedIn, you can also incorporate this Twitter feed into your LinkedIn account by adding Twitter as an application on your LinkedIn profile.

Here is a sample of Fraud PG tweets::

- CMS announces Sunshine regs will be published in Fed. Reg. Dec. 19th. Pre-publication PDF version available at <https://s3.amazonaws.com/public-inspection.federalregister.gov/2011-32244.pdf> - December 14.
- Medtronic Settles Kickback Allegations for \$23.5 Million. <http://www.justice.gov/opa/pr/2011/December/11-civ-1623.html> - December 13.
- OIG posted its first weekly podcast (the first of 11) on its exclusion authority and the effects of exclusion at http://oig.hhs.gov/newsroom/video/2011/heat_modules.asp - December 5.
- Growing trend of DOJ pursuing criminal cases against health care providers for fraudulent billings to private payers. <http://www.justice.gov/usao/txs/1News/Releases/2011%20November/111114%20Chavez.htm> - November 30.
- Oral argument in the *Tuomey* case appeal in the 4th Circuit is scheduled for January 20, 2012 - important Stark law issues to be decided - November 23.

The Fraud PG is seeking volunteers to assist in maintaining and tweeting from the [@AHLA_FraudAbuse](https://twitter.com/AHLA_FraudAbuse) handle. If you are interested in volunteering, please contact Vice Chair of Research and Website [Gary Herschman](https://twitter.com/AHLA_FraudAbuse).





Healthcare Fraud and Abuse Bootcamp Webinar Series January-June 2012

Join us for one or more lunchtime Fraud Bootcamp webinars, led by the nation's top healthcare experts.

Part I: Fraud Healthcare Primer

(January 17, 2012, 1:00-2:30 pm Eastern)

Part II: Stark Law: Soup to Nuts

(February 14, 2012, 2:00-3:30 pm Eastern)

Part III: The Federal Anti-Kickback Law: An Overview, Recent Enforcement Trends and Impact of Healthcare Reform

(March 1, 2012, 12:00-1:30 pm Eastern)

Part IV: Federal Civil False Claims Act

(April 5, 2012, 1:00-2:30 pm Eastern)

Part V: Compliance and Transactions

(May 3, 2012, 1:00-2:30 pm Eastern)

Part VI: Trends in Government Enforcement and Best Practices for Investigating and Defending Healthcare Fraud Actions

(June 7, 2012, 1:00-2:30 pm Eastern)

If you are:

- » In-house counsel working in the healthcare industry
- » General healthcare practitioner
- » General litigator
- » Government enforcement and fraud and abuse practitioner

If you need:

- » A refresher introduction to fraud and abuse principles, or
- » A comprehensive review of one or more substantive topics

Register for the entire Bootcamp or select individual sessions à la carte. Special reduced rates are available, including members-only discounts, and reduced prices for government and academic members, solo practitioners, and students.

Register today at www.healthlawyers.org/webinars or call (202) 833-1100, prompt #2.

This bootcamp webinar series is brought to you by the Fraud and Abuse Practice Group, and is co-sponsored by the Healthcare Liability and Litigation, Hospitals and Health Systems, Physician Organizations, In-House Counsel, and the Regulation, Accreditation, and Payment Practice Groups.





American Health Lawyers Association

Call for Practice Group Leaders/Participation

If you would like to submit a nomination for yourself or on behalf of another member for the position of chair or vice chair of a Practice Group, or are interested in becoming more active in your Practice Group, please complete this form, respond to the appropriate questions, and attach a curriculum vitae.

Yes, I'm interested in being considered for Practice Group leadership:

- Nominating Self (please print or type) Nominating another member (please print or type)

Name _____ Title _____

Firm/Organization _____

Street Address _____

City _____ State _____ ZIP+4 _____

Phone _____ Fax _____ Email _____

Leadership

- Practice Group Chair (one-year appointment) Practice Group Vice Chair (one-year appointment)

Other Volunteer Opportunities

- | | |
|--|--|
| <input type="checkbox"/> Discussion list moderator | <input type="checkbox"/> Write a Practice Group feature article to be published in <i>AHLA Connections</i> |
| <input type="checkbox"/> Practice Group website monitor | <input type="checkbox"/> Contribute to a Practice Group toolkit |
| <input type="checkbox"/> Write a Practice Group member briefing | <input type="checkbox"/> Assist in planning a Practice Group webinar or roundtable discussion |
| <input type="checkbox"/> Write a Practice Group newsletter article | <input type="checkbox"/> Monitor current events for Practice Group email alerts |
| <input type="checkbox"/> Serve as editor for a publication | |

For the following Practice Groups and/or Task Forces

- | | |
|---|--|
| <input type="checkbox"/> Antitrust | <input type="checkbox"/> Medical Staff, Credentialing, and Peer Review |
| <input type="checkbox"/> Business Law and Governance | <input type="checkbox"/> Payors, Plans, and Managed Care |
| <input type="checkbox"/> Fraud and Abuse | <input type="checkbox"/> Physician Organizations |
| <input type="checkbox"/> Health Information and Technology | <input type="checkbox"/> Regulation, Accreditation, and Payment |
| <input type="checkbox"/> Healthcare Liability and Litigation | <input type="checkbox"/> Tax and Finance |
| <input type="checkbox"/> Hospitals and Health Systems | <input type="checkbox"/> Teaching Hospitals and Academic Medical Centers |
| <input type="checkbox"/> In-House Counsel | <input type="checkbox"/> Accountable Care Organization Task Force |
| <input type="checkbox"/> Labor and Employment | <input type="checkbox"/> Enterprise Risk Management Task Force |
| <input type="checkbox"/> Life Sciences | <input type="checkbox"/> Healthcare Reform Educational Task Force |
| <input type="checkbox"/> Long Term Care, Senior Housing, In-Home Care, and Rehabilitation | |

Please provide the following on an attached sheet if you are interested in a leadership position:

- (1) Please describe the candidate's prior service and participation in the Association.
- (2) What contribution would the candidate expect to make in the leadership position or activity?

Diversity Statement: In principle and in practice, the American Health Lawyers Association values and seeks diverse and inclusive participation within the Association regardless of gender, race, creed, sexual orientation, national origin, or disability. The Association welcomes all members as it leads health law to excellence through education, information, and dialogue.

Please return this form along with your supporting material by February 10, 2012, to Magda Wencel, AHLA, 1620 Eye Street, NW, 6th Floor, Washington, DC 20006, Fax (202) 833-1105, mwencel@healthlawyers.org.



REACH GREATER HEIGHTS BECOME A MENTOR

**Add your mentoring profile by going to
www.healthlawyers.org/mentoring.**



AMERICAN
HEALTH LAWYERS
ASSOCIATION

1620 Eye St NW,
6th Floor
Washington DC 20006